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(71)(72) Applicant and Inventor: SHAW, Thomas, J. [US/US]; 1510 Hillcrest Drive, Little Elm, TX 75068 (US).

(74) Agents: WATSON, Harry, J. et al.; Locke Purnell Rain Harrell, Suite 2200, 2200 Ross Avenue, Dallas, TX 75201 (US).

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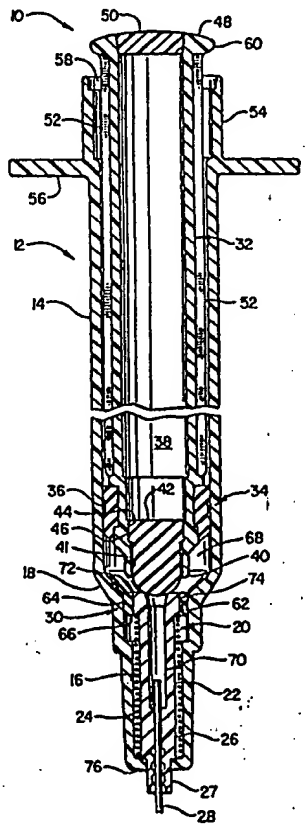
(54) Title: SYRINGE PLUNGER ASSEMBLY AND BARREL

(57) Abstract

A tamper proof retractable non-reusable syringe has a one-piece hollow outer body (12) with a barrel (14) for a slidable plunger (32), a transition zone, and a smaller diameter nose portion (16). An elongated needle holder (22) and spring combination is installed from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted part of the transition zone where the nose begins. The plunger has an opening (41) with a dislodged stopper (42) for receiving parts of the retraction mechanism. The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is sliding removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection. In a second embodiment the head of the needle holder is clamped, and held by constricting forces imposed by stress on the outer body induced by interference fit. Release occurs by slight expansion on the barrel by contact of the plunger tip with a small internal ramp in the outer barrel. Both embodiments have a plunger cap configured to enter an opening in the outer body to provide an additional tamper proof feature. The retraction cavity is provided with venting structures to assure that all uninjected fluid is retained within the syringe body.



SYRINGE PLUNGER ASSEMBLY AND BARREL

CROSS REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of copending patent application serial number 08/537,242 filed September 29, 1995 entitled Tamperproof Retractable Syringe which in turn was a continuation of serial number 08/438,954 filed May 11, 1995, now U.S. Patent No. 5,578,011 all by the same inventor for which benefit is claimed under 35 U.S.C. §120.

FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe and components suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe.

There are a number of syringes of different designs which have needles which will retract at the end of the injection cycle. Most of these have never reached the market because of various deficiencies. Prime among the usual deficiencies of the prior art are problems of complexity, reliability, cost and ease of use. The most commonly used syringes

flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release, cumulating in excessive force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest number of easily made parts.

The syringe plunger assembly has a combination of features not found in a prior art syringe. A head end which acts like a piston when installed in a syringe barrel has a reduced diameter front end having an opening and a dislodgeable stopper slidingly mounted in the opening projecting forwardly from the tip. Cooperating lands within the opening and on the head of the dislodgeable stopper seal the opening into the hollow interior of the plunger. The area of the stopper is relatively small when compared to the area exposed to the piston,

elongated barrel with an end cap for depression of the plunger extending from an opening in the back of the barrel. The head of the plunger, which has a retraction cavity for receiving parts of a retraction mechanism, moves in slidable sealed contact with the interior of the barrel.

A retraction mechanism is lodged in the nose of the body. The retraction mechanism comprises an elongated needle holder and spring combination wherein the needle holder has an elongated body with a needle holding portion in front and a head in back. The head of the needle holder has a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface along an interface oriented in the direction of retraction to produce a holding force on the needle holder when installed in the nose in the unretracted position. The needle holder and spring are easily installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said cooperating inwardly and outwardly facing surfaces while compressing the spring and thereby producing a holding force on the needle holder in opposition to the retraction force applied to the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the

wall. Upon further depression of the plunger from the second position to the retraction position, the frictional holding force on the needle holder is reduced until the retraction force provided by the spring exceeds the remaining holding force and the needle holder and needle connected thereto are ejected into the cavity carrying the dislodged stopper along with them. The dislodging of the stopper and the retainer member alone make the syringe non-reusable. The plunger cannot be removed after retraction because the graspable end cap enters an opening at the back of the barrel when the plunger is depressed to the retraction position to prevent tampering after retraction.

The retraction cavity of the plunger is preferably vented to prevent a puff of air coming forward at the instant of retraction from blowing a tiny amount of retained fluid from the nose. This condition can occur if the plunger is fully depressed to release the needle holder and dislodge the stopper while the needle is physically restrained from retracting by the septum of a vial which has just been filled with fluid from the syringe. The thumb cap at the rear of the syringe is preferably provided with channels in fluid communication with the interior in cooperation with a closure removably installed in a centrally located opening in the thumb cap. One or more stepped portions of the opening and closure provide seating for the closure. Undercut portions at the side of the closure together with grooves in the interior surface of the plunger wall create passages for air to vent through channels on the thumb cap. This structure prevents air from being trapped by the user's thumb when the thumb cap is pressed to fire the syringe. One or more slots at the back of the barrel around the opening which receives the thumb cap prevent vented air from being trapped by the user's thumb when the plunger is fully depressed.

The syringe has a high blowout pressure and a low plunger thumb force required to cause retraction. Blowout pressure is the fluid pressure operating on the stopper and retainer

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space with will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose. Significant variations in the holding force on the needle holder and the dislodging force on the stopper due to slight variances in the tolerance of the mating parts is avoided because the longitudinal wall of the outer body has some flexibility. The wall can spread outwardly slightly and the stopper and head of the needle holder can compress slightly radially and expand slightly in the longitudinal direction to avoid significant changes in the holding force caused by small changes in the actual diameters. Consistency in the amount of retraction force is thereby provided and economy is assured.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cross section along the central axis of a first embodiment of the invention with the plunger positioned in a first position at the end of an injection cycle;

Figure 2 is the syringe of Figure 1 with the plunger depressed additionally to dislodge the stopper at a second position of the plunger wherein the tip of the plunger is ready to operate the retraction mechanism;

plunger and end cap of Figure 9 and 10 along line 11-11 showing the preferred closure;

Figure 12 is a cut away elevational view of the plunger end cap and closure of Figure 11 as the thumb cap is just being received into the barrel opening;

Figure 13 is a plan view of a first alternative thumb cap and closure combination utilizing a flat sided closure and four channels in the thumb cap;

Figure 14 is a cut away elevational view on the lines 14-14 of the thumb cap closure combination of Figure 13;

Figure 15 is a plan view of a second alternate thumb cap and closure combination with four channels in the thumb cap and undercut portions to provide a vent passage;

Figure 16 is a cut away elevational view on the lines 16-16 of the combination of Figure 16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. Parts with a subscript letter are mean to illustrate a minor variation of a part with the same number. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are understood to be preferably circular and symmetrical as is conventional for syringes. The drawings reflect a syringe structure typically having a 1cc to 3cc injection fluid capacity.

Figure 1 shows the structure of the first embodiment generally referred to by reference numeral 10. Syringe 10 has a one piece hollow outer body 12. Body 12 has a longitudinally extending wall comprising an elongated barrel 14 and a nose 16 with a transition zone 18 connecting the barrel and nose. A front mounted retraction mechanism lodged in the nose is generally referred to by the reference numeral 20. It comprises the combination of an elongated needle holder 22 and spring 24. The needle holder has an

the plunger can no longer be grasped after retraction has occurred because end cap 48 is depressed into an opening.

The wall of outer body 12 and head 30 of the needle holder have mating cooperating smooth surfaces which hold needle holder 22 in the position shown in Figure 1 with spring 24 compressed. Nose 16 has a reduced diameter relative to the barrel. The outer body has a most constricted part where head 30 of needle holder 22 is engaged and held. The outer body has an inwardly facing surface 62 at the most constricted part of the transition zone where nose 16 begins. Similarly, head 30 has an outwardly facing surface 64 configured to cooperate with inwardly facing surface 62 to produce a holding force on needle holder 22 when the retraction mechanism is installed in the nose from the rear. Mating surfaces 62, 64 constitute a sliding interface oriented in the direction of retraction, which seals nose 16. Mating surfaces 62, 64 are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder 22 in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

Head 30 provides a lower boundary for a variable fluid chamber 68 below head 34. Needle holder 22 has a fluid path 70 in fluid communication with fluid chamber 68 and needle 28. Needle holder 22 has a smaller diameter inner head 72 which is part of head 30. Retainer member 66 is coupled to inner head 72 along sliding interface 74 oriented in the direction of retraction. Retainer member 66 is coupled to inner head 72 with a holding force which exceeds a retraction force applied to the underside of inner head 72 by means of the end of compressed spring 24. A reduced diameter portion 27 of needle holder 22 protrudes through an opening in front 76 of nose 16.

46 and could cause stopper 42 to blowout. A frictional holding force is generated at the lands 44, 46 which may be called a dislodging force which must be overcome to slide stopper 42 rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber 68 to the maximum cross sectional area of stopper 42 exposed to pressure in chamber 68 are selected so that the maximum expected thumb force on plunger 32 during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper 42 will not blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In Figure 1, stopper 42 has a forward extension beyond tip 40 which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip 40 is related to the length of lands 44, 46 such that the forward extension of stopper 42 preferably represents about 80 percent of the engaged land length. When stopper 42 is moved back until the front is even with tip 40, as seen in Figure 2, only about 20 percent of engaged land remains. In Figure 2 it can be seen that thumb force on plunger cap 48 has been applied to partially dislodge stopper 42 such that a gap 78 is created and the remaining engaged land area is represented as area 80.

Since I believe the amount of frictional holding force or dislodging force is roughly

friction surface 62. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member 66 off needle holder 22 is reduced and the small remaining engagement area 80 between lands 44, 46 of the plunger and stopper preferably cause stopper 42 to be dislodged before needle holder 22 is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring 24, the retraction position of Figure 3 is reached whereby retraction occurs.

When retraction occurs needle holder 22 moves through opening 41 into cavity 38. The uncompressed length of spring 24 is selected to provide backward movement sufficient to withdraw an injection needle 28 fixed in front portion 26 entirely within outer body 12, carrying dislodged stopper 42 with it. At the same time, cap 48 enters opening 58 of the barrel with peripheral edge 60 closely confined, in order to prevent tampering after retraction. It is immaterial whether cap 48 moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface 62 is provided so that retainer member 66 can move downwardly a sufficient distance to reach the retraction position of Figure 3. After retraction, retainer member 66 preferably remains stuck and prevents any possibility of any one being able to reengage it with the head of needle holder 22. The diameter of land 62 in the area designated 63 can be increased slightly to provide relief for retainer ring 66 as it is pushed down by tip 40.

It is also within the contemplation of the invention that separable retainer member 66 may be removably coupled to inner head 72 of needle holder 22 by means of a relatively small in area "tack" weld which is sufficient to resist the retraction force applied to needle

of the device. All fluid must pass through fluid passage 70.

It can be seen that when the position of Figure 2 is reached the front tip 40 of the plunger presses against retainer ring 66a after stopper 42 is almost dislodged and uncouples the retainer ring 66a from the inner head 72a of needle holder 22a. Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured or otherwise separated so as to separate retainer ring 66 a from inner head 72a thus releasing needle holder 22a from further restraint. They and the force applied by spring 24 causes retraction to occur much as before described and shown in Figure 3.

It is believed that the increased diameter of the raised portion 73 should be within the range of about 1 to 8 thousandths of an inch which may be dictated by the ability of the molding equipment available to produce a consistent bridging portion without defects. It is believed that it may be desirable to employ different polymeric materials for the retainer ring and needle holder to facilitate tack welding, such as a suitable polyvinyl chloride (PVC) for the retainer ring and a suitable polycarbonate plastic material for the needle holder. One way to couple these two parts may be to assemble them and expose them to a temperature of about 120°C for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch. The raised portion creates a high unit pressure where it comes into contact with the inwardly facing surface of retainer 66a. Sonic welding could also be employed. A coating or adhesive which couples the retainer ring to the needle holder and can be uncoupled by means of force applied to the retainer ring by the plunger is also within the contemplation of the invention.

An alternate syringe 82 is disclosed in Figures 5 - 7. In Figure 5, Syringe 82 has a one piece hollow outer syringe body 84. Body 84 has a longitudinally extending wall comprising an elongated barrel 86 and a nose 88 with a transition zone 90 connecting the

part of the transition zone where nose 88 begins. Similarly, head 102 has an outwardly facing friction surface 128 configured to cooperate with inwardly facing surface 126 to produce a frictional holding force on needle holder 94 when the retraction mechanism is installed in the nose from the rear.

Mating surfaces 126, 128 constitute a sliding interface oriented in the direction of retraction, which seal nose 88. Mating surfaces 126, 128 are preferably smooth friction surfaces which have an interference sliding fit when needle holder 94 is installed from the rear whereby a frictional holding force holds needle holder 94 in position by friction between land 126 and head 102 of needle holder 94. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head 106 provides the upper boundary for a variable fluid chamber 130 below head 106. Needle holder 94 has a fluid path 132 in fluid communication with chamber 130 and needle 28. Needle holder 94 is releasably coupled at surfaces or lands 126, 128 with a holding force that exceed the retraction force applied to the underside of head 102 by the end of compressed spring 96. A reduced diameter portion 134 of needle holder 94 protrudes through an opening in front 136 of nose 88. Blowout pressure is not a factor with respect to the needle holder on the alternate embodiment. No amount of pressure will allow needle holder 94 or needle 28 to move forward since the front portion 100 of the needle holder is grounded or bottomed inside front 136 of nose 88.

Blowout pressure is still a factor to be considered in connection with stopper 114. Blowout pressure would be the pressure in chamber 130 produced by thumb force on cap 48 acting on the cross sectional area of stopper 114 which could overcome the holding force, causing stopper 114 to dislodge from opening 112 prematurely. The ratio of the maximum

The barrel is flexible and is spread outwardly a slight amount to the position of Figure 6 just prior to retraction. Here the mating surfaces 126, 128 are separated an amount which reduces the clamping force on the needle holder 94. The spreading shown in Figure 6 is greatly exaggerated for illustration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder 94 from nose 88. By slight further depression of the plunger from the position of Figure 6 to the retracted position of Figure 7, retraction occurs when the retraction force applied by spring 96 exceeds the remaining holding force on needle holder 94. Needle holder 94 then moves through opening 112 into cavity 108 along with a portion of spring 96. The uncompressed length of spring 96 is designed to provide sufficient backward movement to withdraw an injection needle 28 fixed in front portion 94 and carry dislodged stopper 114 with it. At the same time, cap 42 enters opening 138 at the rear of a barrel extension 54 where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp 124 is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper 114 should be dislodged by thumb pressure on plunger 104 before significant resistance develops as angled surfaces 122 begin pushing outwardly on ramp 124. The selection of the location of ramp 24 and the angle of the engaging surfaces make it possible to have a fairly smooth continuous force since the dislodging force continuously decreases as the sliding interface area 116, 118 between the plunger and the stopper is linearly decreased. Because ramp 124 is relatively very small, it is still possible to remove a stepped molding core from the rear of the outer body 84. Alternately, ramp 124 can be the smaller diameter step 125 which avoids reentrant angles whereby resistance to removal of the molding core could occur. After retraction, the back of the plunger is unaccessible and there is no way to reach to stopper or the needle holder

plunger fully after the fluid is discharged to retract the needle. When the plunger is depressed fully to cause retraction, the needle cannot retract normally due to the fact it is frictionally held by the rubber septum of the vial. When the empty syringe is then withdrawn from the vial by pulling the needle out of the septum, it immediately retracts. Droplets of fluid were observed on the vial as soon as retraction took place.

Surprisingly, it was found that a small "puff" of air is the source of this problem. If the needle or needle holder is temporarily restrained and prevented from retracting in the normal manner, a brief puff of forwardly directed air is generated when the needle holder is finally allowed to retract. This puff of air was found to emerge from the front of the syringe causing retained fluid trapped around the needle holder to be blown out of the opening left in the nose when the needle holder retracts. It was discovered that if the hollow interior of the plunger is vented, preferably in the area of thumb cap, this condition does not occur and the fluid is entirely retained within the syringe body.

Figures 9 through 16 illustrate the syringe generally designated as syringe 10 with a modification on the end cap or thumb cap on the plunger to provide for venting of the hollow interior of the plunger which is the retraction cavity. Insofar as possible the original numbering of Figures 1 - 4 is retained with primes used to indicate differences.

Head 34' of plunger 32' is preferably slightly modified from plunger head 34 of Figure 2 in the following respects. The elongated plunger has a longitudinally extending generally tubular wall 140 defining a hollow interior along the length of the plunger. The plunger has a head end 34' in front and a rear end portion 142 with a thumb cap 48' behind. The outer side of wall 140 at head end 34' is sealingly surrounded with a resilient plunger seal member 36' which is like a band with a pair of separated raised rings 144. Plunger seal

forces without blowing out the stopper during an injection. The cooperating lands on the inside of the plunger head and the stopper have sufficient longitudinal length to allow dislodgeable stopper 42 to move the fixed distance between its initial extension at 146 and tip 40 in sliding response to forward movement of the plunger after front 146 of stopper 42 contacts a stop.

As indicated in Figures 1 - 3, front 146 of the stopper 42 encounters head 72 of needle holder 22 which serves as a stop. The fluid opening in head 72 of needle holder 22 is preferably provided with some fine slots or grooves so that fluid can continually enter fluid path 70 as the plunger moves from the position of Figure 1 to that of Figure 2. As the position of Figure 2 is reached, the holding force on stopper 42 is reduced by substantial disengagement of the cooperating lands 44, 46 in preparation for dislodgement of the stopper, without unsealing the hollow interior/retraction chamber 38 within plunger 32'. A notch 148 is preferably provided in the tip to prevent trapping fluid at the tip.

Thumb cap 48' at the rear end portion 142 of plunger 32' includes one or more channels 150 which receive vented air from hollow interior 38. Thumb cap 48' has an opening 152 for a closure 154 best seen in Figures 10 and 11. Channels 150 are open at the top for ease of molding although closed channels could also be used.

Figure 10 shows an enlarged top plan view illustrating the use of three channels 150 in combination with a preferred closure 154 installed in circular opening 152. Figure 11 best shows how the channels 150 receive vented air from hollow interior 38. Closure 154 preferably has a stepped outer surface comprising a rear step 156 which rests in opening 152, an intermediate step 158 which rests in an enlarged portion 160 of the inner side of wall 140 and a front step 162 which rests against inner surface 164 of wall 140. In effect, these structures provide convenient seating for closure 154. Steps 158 and 162 are conveniently

14. In this embodiment, four channels 150 are provided in thumb cap 48''. Closure 174 has four flat side portions 176 spaced around the periphery at 90° intervals, each in fluid communication with a channel 150. A gap is created at each flat side between the flat sides 176 and the opening 152' which are in fluid communication with interior 38 to create a flow passage for air from interior 38 through the gap along the flat side then into channel 150. Annular groove 178 in closure 174 may be used to fluidly connect each of the flat areas 176 at the level of channels 150. In addition to equalizing air flow, the annular groove allows venting of air regardless of the angular orientation of closure 174 with respect to thumb cap 48''.

A second alternate embodiment has the same thumb cap 48'' with a modified closure 180. Closure 180 has a head 182 which snugly fits within opening 152' which is at the back of the plunger. Opening 152' is only slightly larger than the interior of the plunger to provide a seat for the closure. Four undercut portions 186 are each in joint fluid communication with the interior 38 and one of the channels 150 to create a flow passage from the interior 38. Closure 180 effectively seals the opening 152' so that no fluid particles can escape from the opening. As in the previous embodiment, an annular groove 178 bridges each undercut portion opening into a corresponding channel 150 thereby tying the undercut portions together in fluid communication regardless of the angular orientation of the parts.

In operation, there are many advantages to the improved combination disclosed herein. The diameter of the stopper in both embodiments and the slidable retaining ring member in the first embodiment, in relation to the diameter across the fluid chamber, makes it possible to produce a syringe which withstands high blowout pressure. By minimizing the effective surface area exposed to the pressurized fluid during an injection, the syringe will

Systems, 540 Maryville Centra Drive, St. Louis, Missouri and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal diameter is stepped to greater diameters from front to back for molding around a non-collapsible core which can be extracted from the rear. The same is true for the plunger.

Assembly is greatly simplified and can be accomplished with high speed mechanized equipment. The needle holder and spring are installable from the rear of the barrel without the needle. In the first embodiment the retainer member is forced fit over the inner head of the needle holder and the assembly together with the uncompressed spring are pushed forward and held by sliding engagement of the cooperating inwardly and outwardly facing surfaces while compressing the spring. The front of the needle holder passes through an opening in the nose which makes it easy to install the needle from the front by conventional means. The alternate embodiment is installed the same way except that there is no separable retainer member around the head of the needle holder.

The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle

a nonexclusive, nontransferable irrevocable, paid up license to the invention as set forth in the priority documents.

wherein the plunger is provided with a venting structure in fluid communication with the retraction cavity to reduce pressure buildup in the retraction cavity during retraction so that any liquid remaining in the syringe just prior to retraction is not expelled from the nose of the syringe.

2. The combination of Claim 1 wherein the venting structure for the retraction cavity is formed at the back end portion of the plunger.

3. The combination of one of Claims 1 - 2 wherein the venting structure includes a channel in the thumb cap which receives vented air from the retraction cavity.

4. The combination of one of Claims 1 - 3 wherein the venting structure includes a channel in the wall of the plunger which receives vented air from the retraction cavity.

5. The combination of one of Claims 3 or 4 wherein said channel in the thumb cap and said channel in the wall of the plunger form a flow passage in fluid communication with the retraction cavity.

6. The combination of Claim 5 wherein the rear end portion of the plunger has an internal surface comprising a groove in fluid communication with said flow passage.

7. The combination of Claim 6 wherein said groove comprises an annular groove.

8. The combination of one of Claims 1 - 7 wherein the back end portion of the plunger contains an opening large enough to receive the dislodgeable stopper during installation of the stopper in the head of the plunger and includes a closure for the opening to form all or part of said thumb cap.

9. The combination of Claim 8 wherein said closure has at least one cut away side portion which forms part of the venting structure.

14. A tamperproof retractable non-reusable syringe structure designed to have a high blowout pressure coupled with a low retraction force, comprising:

a hollow outer body having a longitudinally extending wall comprising an elongated barrel having a back end portion with an opening behind and a nose in front, said nose having a reduced cross-sectional area relative to the barrel;

a retraction mechanism having retractable parts comprising an elongated needle holder and spring combination mounted in the nose portion of the barrel with the needle holder temporarily held in a use position with a needle attached to the needle holder extending from the nose of the barrel and a fluid path through the needle and needle holder leading to a variable fluid chamber in the barrel;

a hollow plunger handle assembly disposed partially within the elongated barrel of the outer body, the plunger having a head in front with a piston fixedly mounted thereon in slidable sealed contact with the interior of the barrel, a back end portion having a graspable end cap and a retraction cavity therein, the plunger head having a tip in front defining an opening into the retraction cavity and a separate dislodgeable stopper slidingly sealing the opening, said stopper having a front end portion extending a distance beyond the tip, the stopper being capable of sliding relative to the plunger back to the tip without unsealing the opening and without completely dislodging in response to forward motion of the plunger after the front end portion of the stopper has come into contact with the needle holder;

the combined head of the plunger and the stopper defining the upper boundary of the variable fluid chamber;

the plunger being movable to a second position while expelling fluid contained in the variable chamber through the fluid path in response to thumb pressure on said cap, said second position comprising the end of an injection cycle including sliding of the stopper said

pressed down, received and recessed in the opening in the back end portion of the barrel of the syringe body.

19. The tamperproof retractable non-reusable syringe structure of Claim 16 wherein the back end portion of the plunger has an internal surface with at least one groove in fluid communication with said channel in the thumb cap to comprise said at least one vent passage.

20. The tamperproof retractable non-reusable syringe structure of Claim 19 wherein the back end portion of the barrel of the syringe body includes at least one slot which allows vented air to escape without being trapped by users thumb during retraction when the thumb cap is pressed down and received in the opening of the barrel at the back of the syringe body.

21. The tamperproof retractable non-reusable syringe structure of Claim 15 wherein the closure has a headed portion fitted in the opening at the rear end of the plunger and a depending skirted side containing an undercut configured to reside in fluid communication jointly with the retraction cavity and at least one channel in the thumb cap to comprise said at least one vent passage.

22. The tamperproof retractable non-reusable syringe structure of Claim 21 wherein the back end portion of the barrel of the syringe body includes at least one slot which allows vented air to escape without being trapped by a user's thumb during retraction when the thumb cap is pressed down and received in said opening in the barrel at the back of the syringe body.

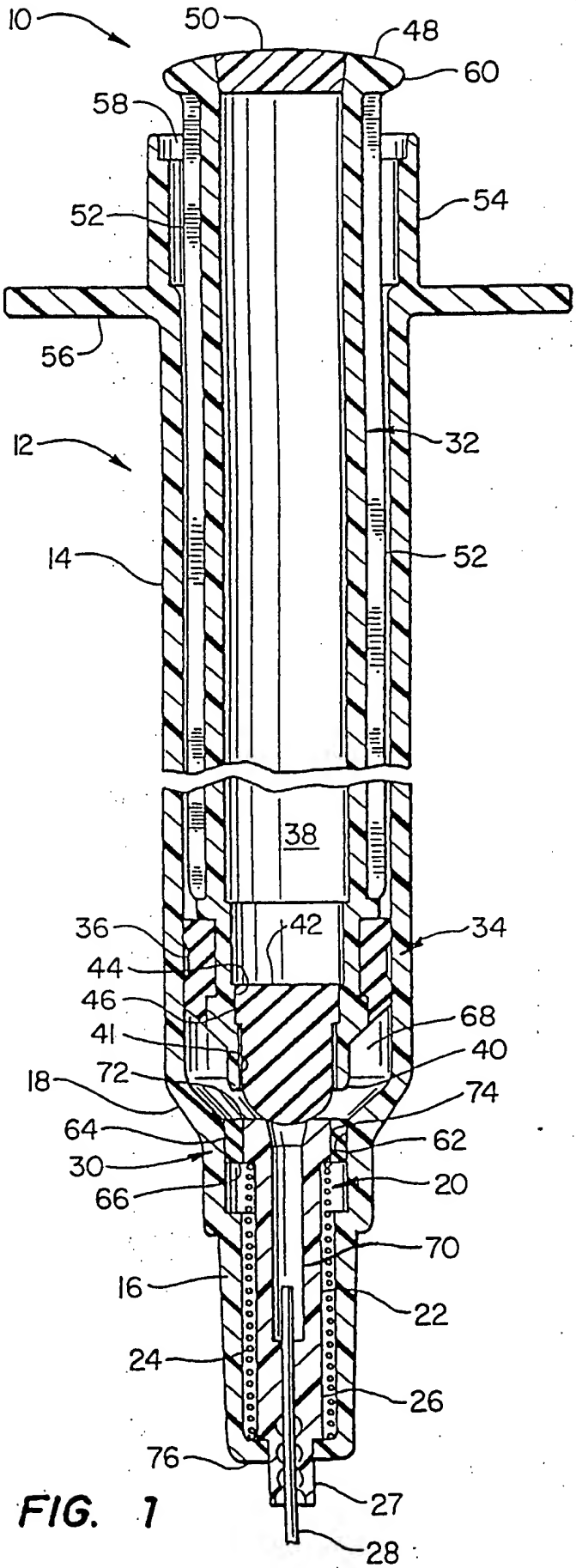

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FIG. 1

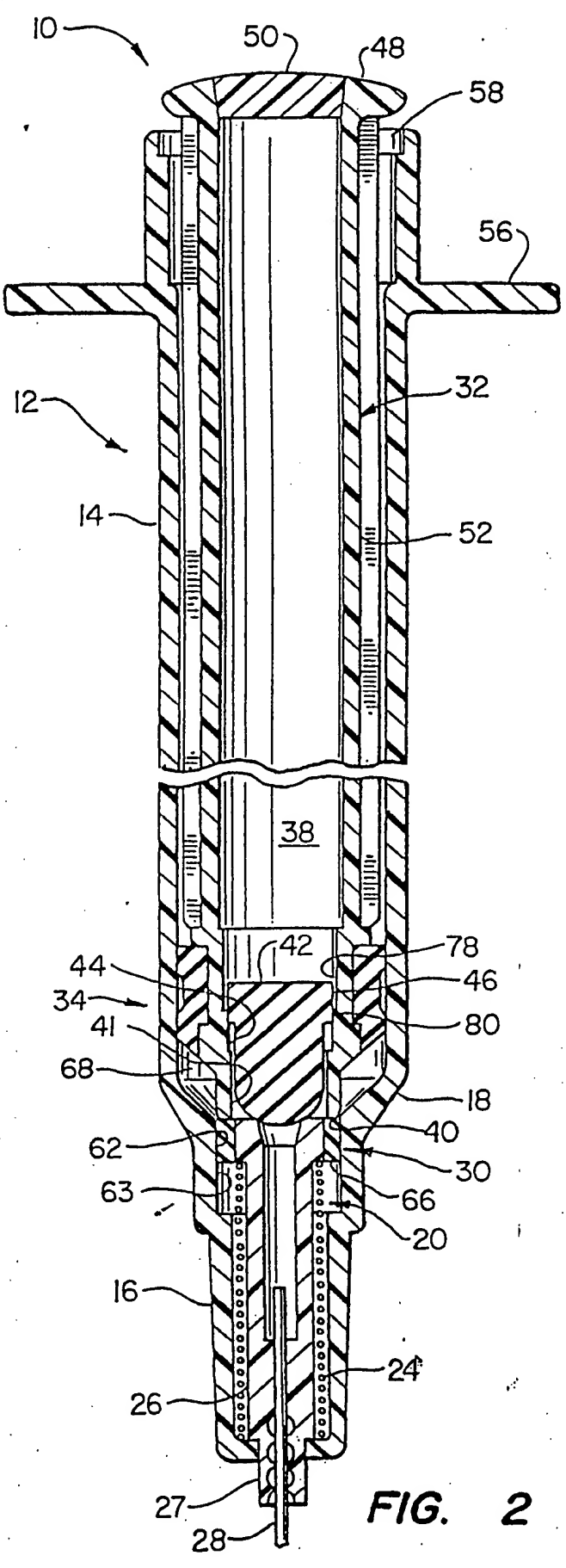
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FIG. 2

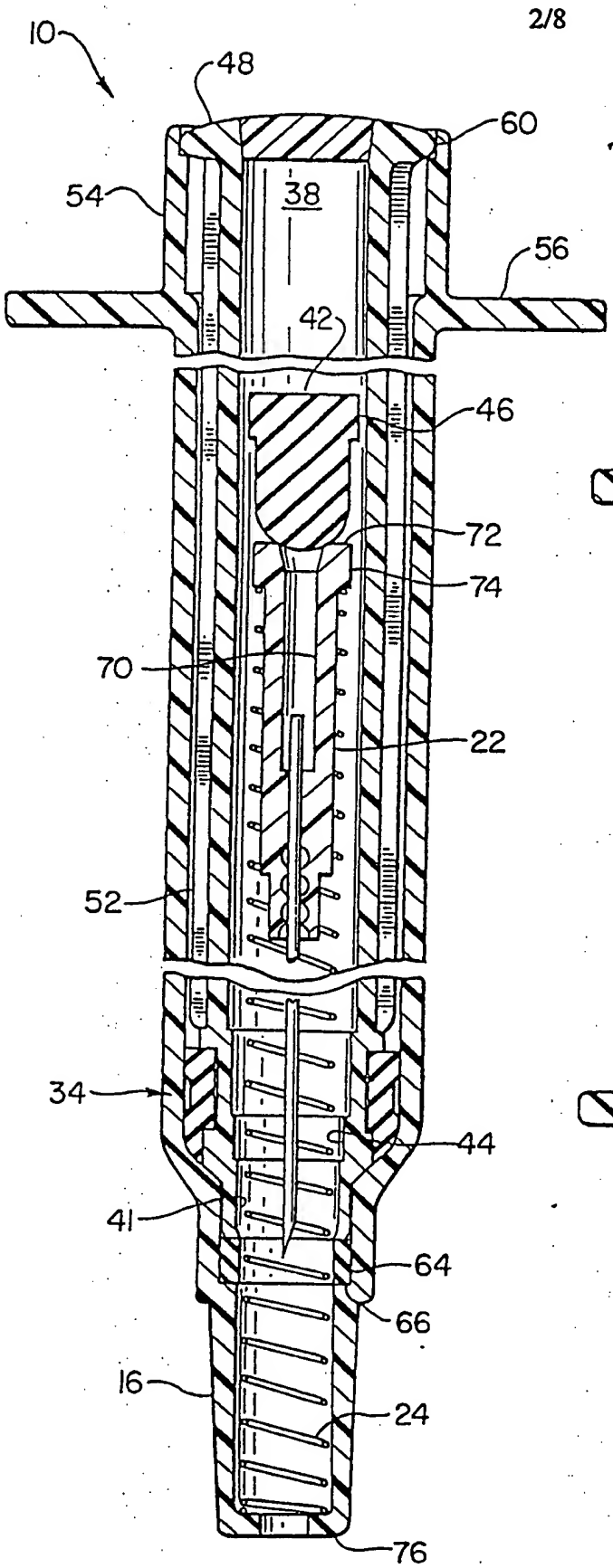

FIG. 3

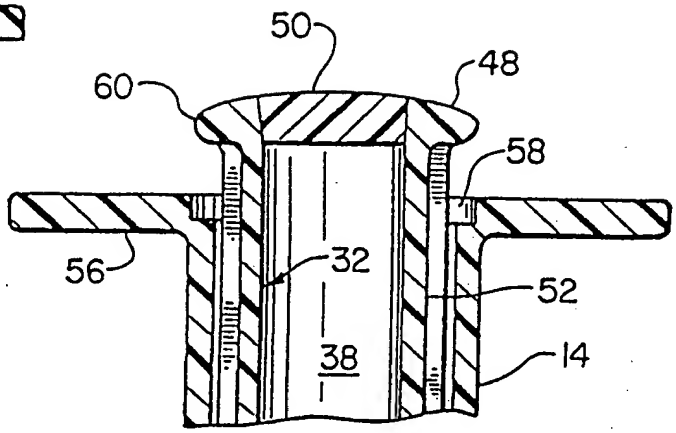

FIG. 4A

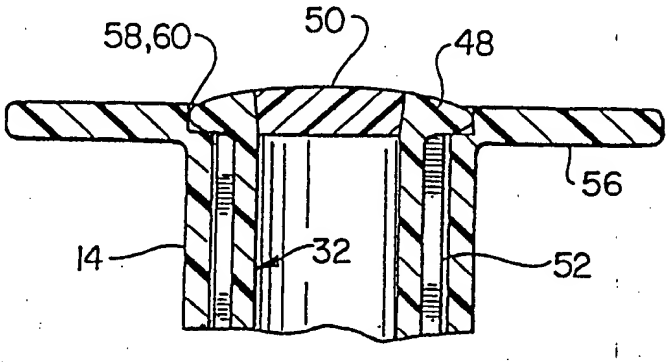

FIG. 4B

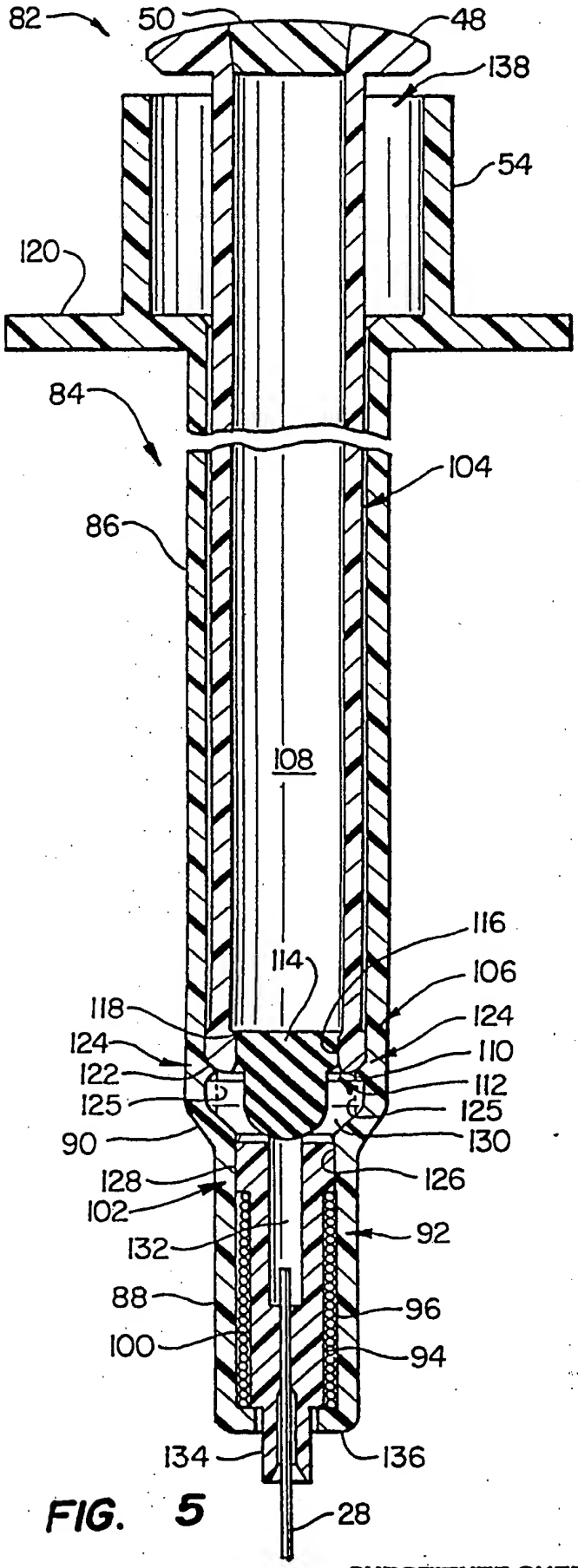
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FIG. 5

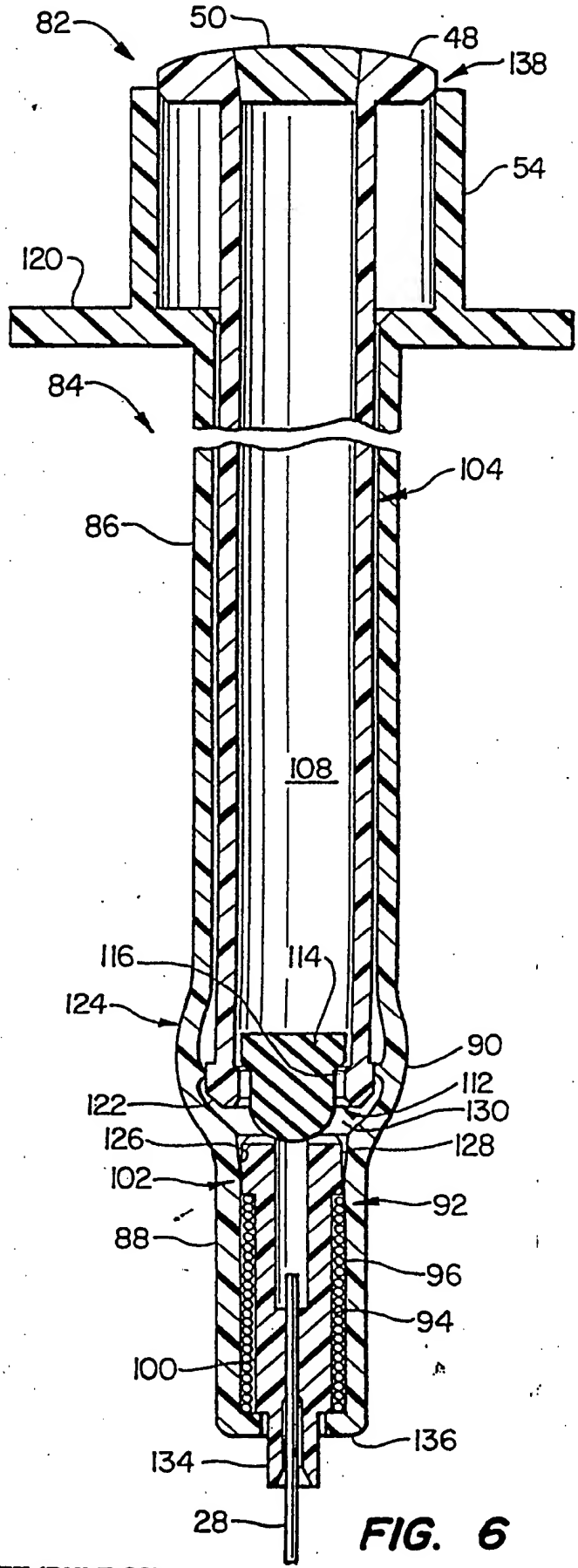
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FIG. 6

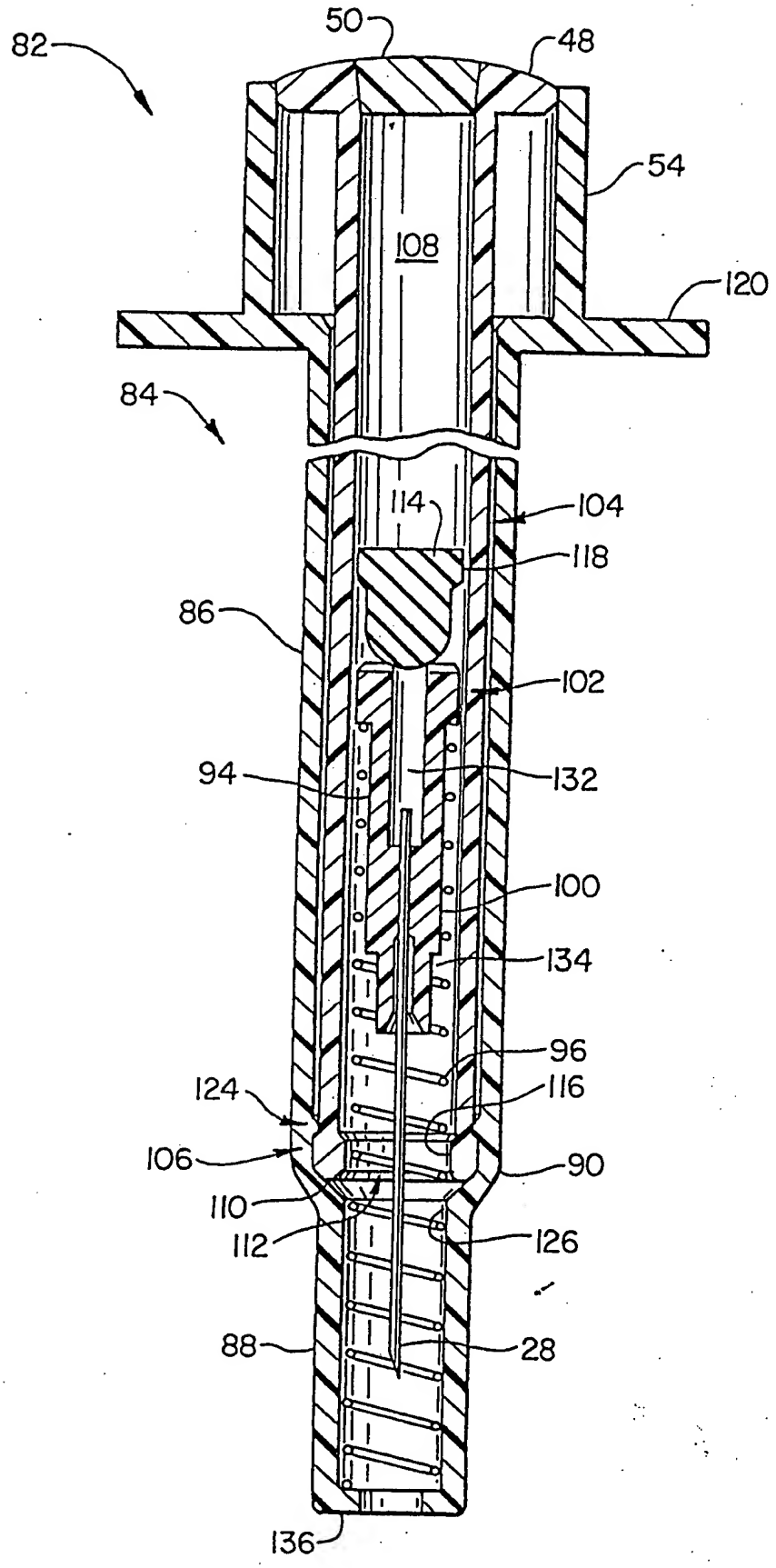
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FIG. 7

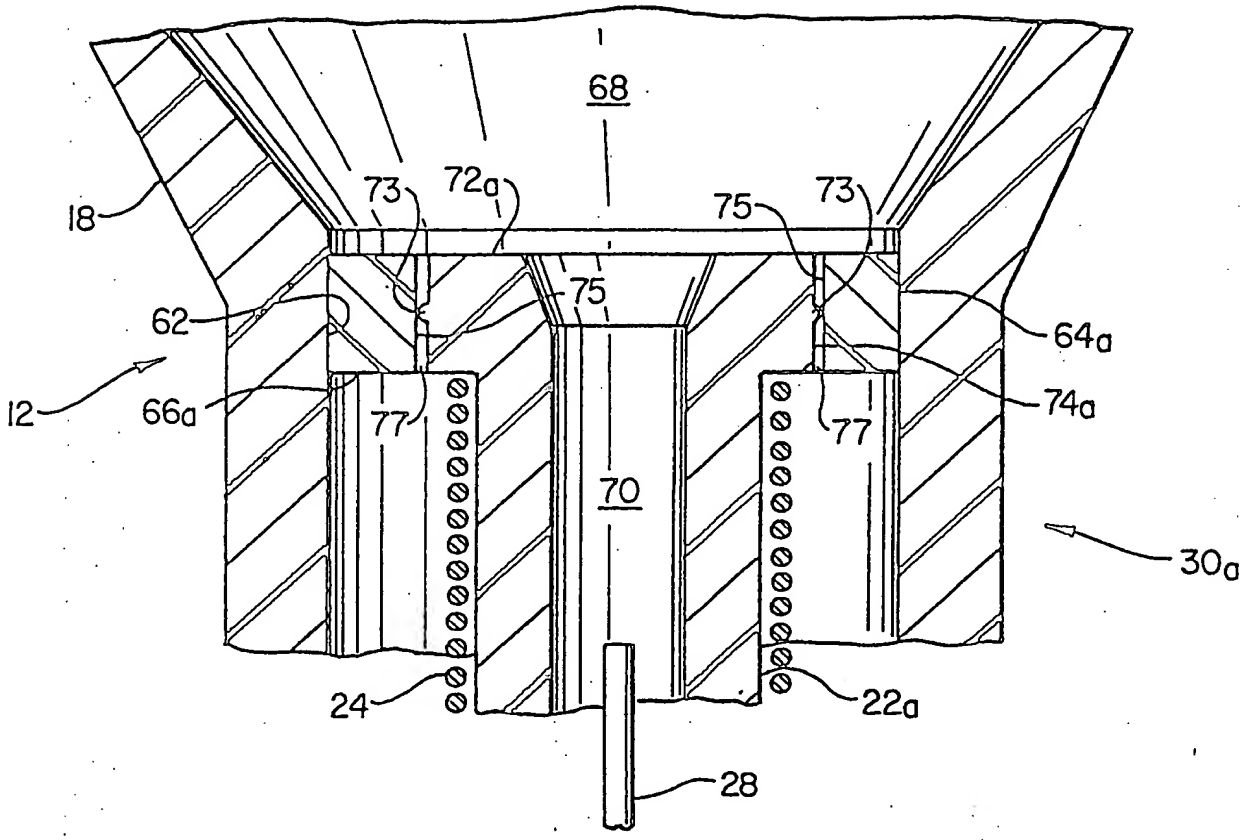

FIG. 8

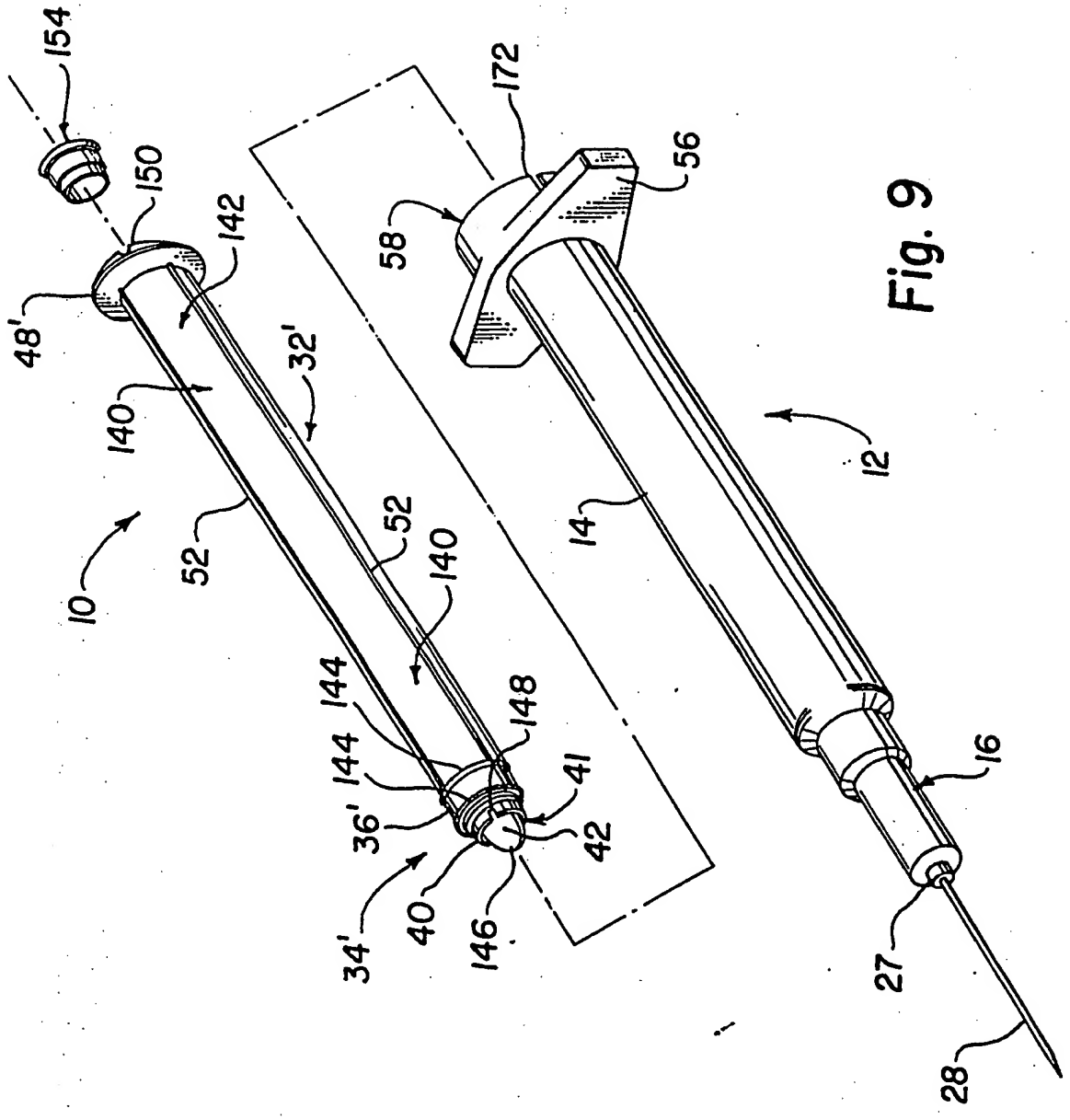
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Fig. 9

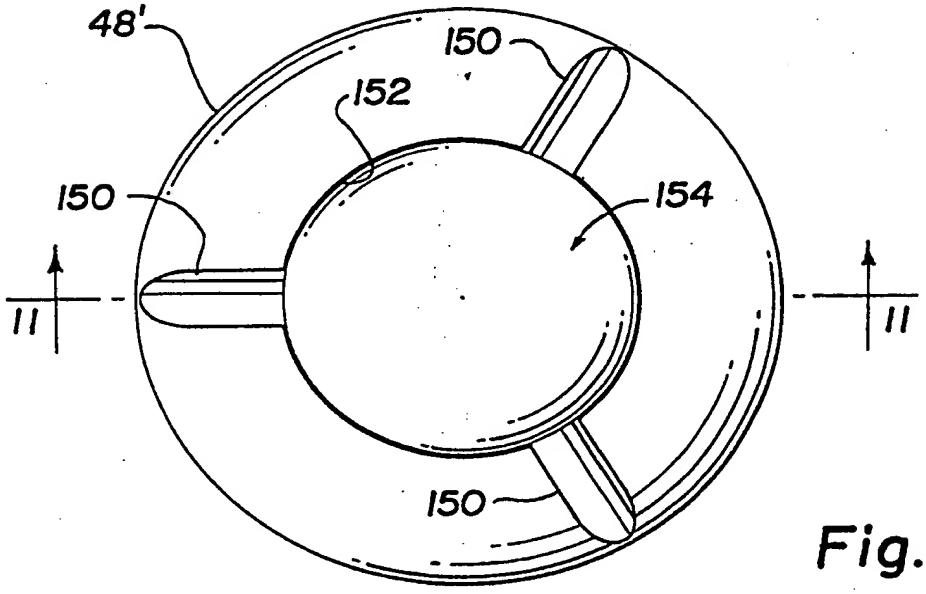
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Fig. 10

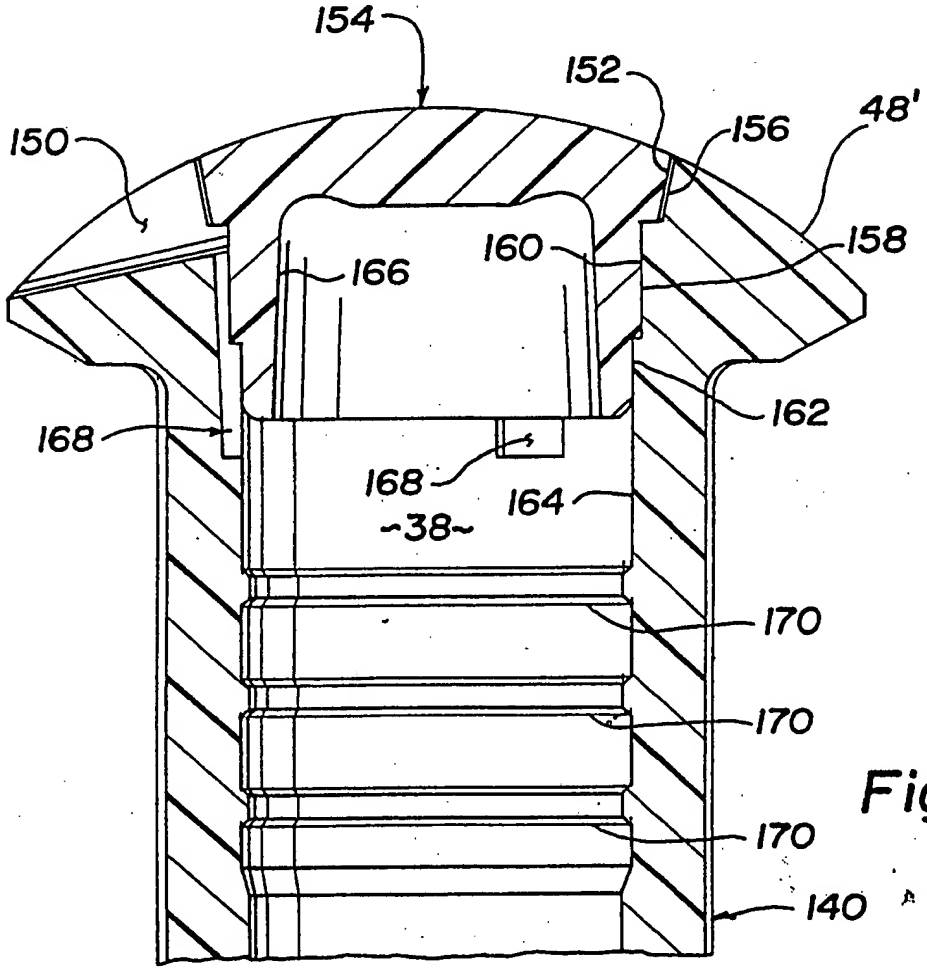
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Fig. 11

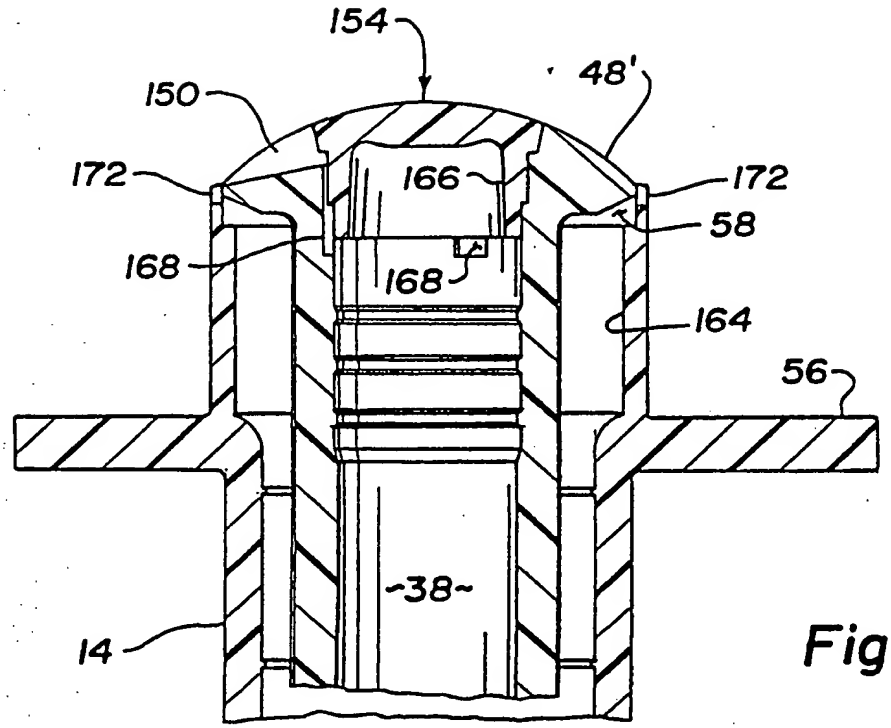

Fig. 12

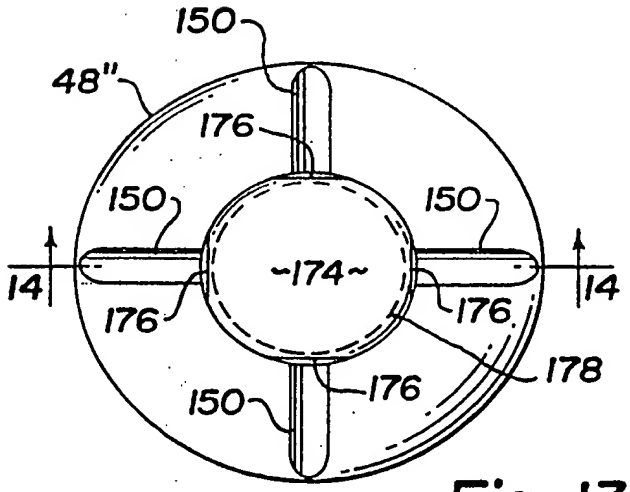

Fig. 13

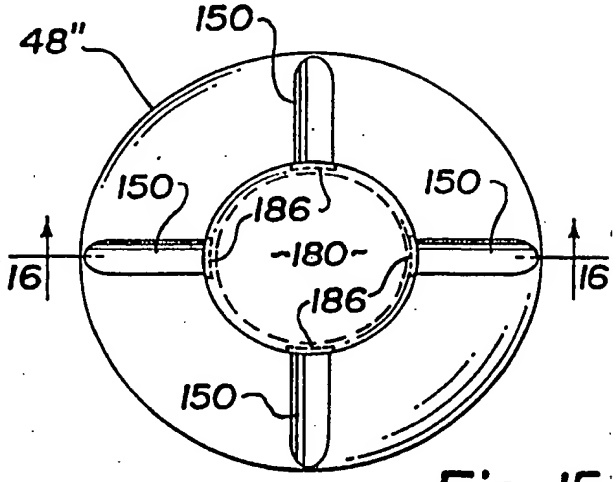

Fig. 15

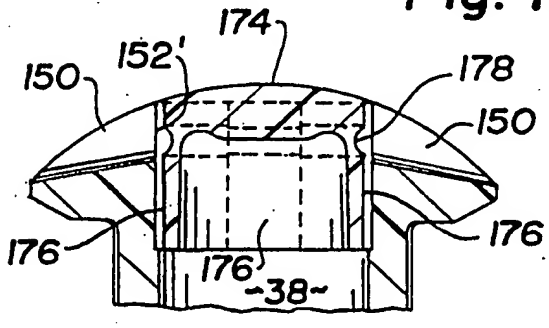

Fig. 14

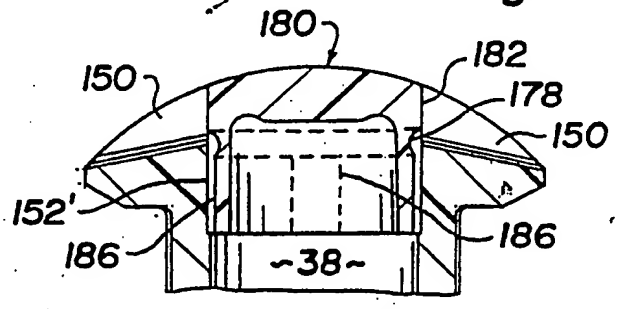

Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/07361

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 5/00
US CL :604/110
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/187, 192, 195, 198, 218, 220, 263

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,838,863 A (ALLARD et al) 13 June 1989, entire document.	1-22
A	US 4,955,870 A (RIDDERHEIM et al) 11 September 1990, entire document.	1-22
A	US 4,747,831 A (KULLI) 31 May 1988, entire document.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 18 MAY 1998	Date of mailing of the international search report 23 JUN 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN D. YASKO Telephone No. (703) 308-2986

Form PCT/ISA/210 (second sheet)(July 1992)*